

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committee; Pediatric Advisory Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a Pediatric Advisory Committee in the Office of the Commissioner. Elsewhere in this issue of the **Federal Register**, FDA is publishing a document requesting nominations for the membership on this committee. This document adds the Pediatric Advisory Committee to the agency's list of standing advisory committees in 21 CFR 14.100.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Authority for the committee being established will end on June 18, 2006, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jan Johannessen, Office of Science and Health Coordination (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463) (5 U.S.C. app. 2); section 904 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394), as amended by the Food and Drug Administration Revitalization Act (Public Law 101-635); section 14 of the Best Pharmaceuticals for Children Act (Public Law 107-109), as

amended by section 3(b)(2) of the Pediatric Research Equity Act of 2003 (Public Law 108–155), and 21 CFR 14.40(b), FDA is announcing the establishment of the Pediatric Advisory Committee by the Commissioner. The Best Pharmaceuticals for Children Act, as amended by the Pediatric Research Equity Act of 2003, provides for the establishment of this committee. This committee will provide advice and make recommendations to the Commissioner of Food and Drugs on matters relating to pediatric therapeutics, pediatric research, and any other matter involving pediatrics for which the Food and Drug Administration has regulatory responsibility. The committee will also advise and make recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

The Pediatric Advisory Committee will be composed of a core of 12 voting members including the chair. Members and the chair are selected by the Commissioner of Food and Drugs (the Commissioner) or designee from among the authorities knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. The core of voting members shall also include one member from a relevant patient or patient family organization and may include one technically qualified member, selected by the Commissioner or designee who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the committee may include one nonvoting member who is identified with industry interests and one nonvoting member who represents a pediatric health organization.

Therefore, the agency is amending 21 CFR 14.100(a) as set forth below.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE:

■ 1. The authority citation for 21 CFR part 14 is revised to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b 264; Pub. L. 107–109; Pub. L. 108–155.

■ 2. Section 14.100 is amended by adding paragraph (a)(3).

§ 14.100 List of standing advisory committees.

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(a) * * *

(3) *Pediatric Advisory Committee.*

(i) Date established: June 18, 2004.

(ii) Function: Advises on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which the Food and Drug Administration has regulatory responsibility.

Dated: July 27, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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